



Virginia  
Regulatory  
Town Hall

townhall.virginia.gov

## Notice of Intended Regulatory Action (NOIRA) Agency Background Document

|  |  |
|--|--|
| <b>Agency name</b>                                 | State Board of Health  |
| <b>Virginia Administrative Code (VAC) citation</b> | 12 VAC5 – 475 – et seq.  |
| <b>Regulation title</b>                            | Virginia Organ and Tissue Donor Registry   |
| <b>Action title</b>                                | Amend the Virginia Organ and Tissue Donor Registry regulation for clarity, efficiency and effectiveness. |
| <b>Date this document prepared</b>                 | February 13, 2008  |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Purpose

*Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.*

To fulfill the statutory mandate to review its regulations governing the Virginia Organ and Tissue Donor Registry and to protect the citizens of the Commonwealth, the Board of Health seeks to begin a review of proposed amendments to the Virginia Donor Registry, formerly referred to as the Virginia Organ and Tissue Donor Registry. The goals of the Board are to enhance the clarity of the regulations and to achieve improvements that will be reasonable, prudent and will not impose an unnecessary burden on users of the Virginia Donor Registry or the public.

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

The state legal basis for this action is § 32.1-292.2 of the Code of Virginia. This statute provides the authority for the State Board of Health, in consultation with the Virginia Transplant Council, to promulgate regulations necessary to create, compile, maintain, modify as necessary, and administer the Virginia

Donor Registry. The imperative form of the verb “shall” is used in §32.1-292.2, making the Board’s authority to regulate mandatory rather than discretionary.

### Need

*Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.*

The current regulations were the first to be promulgated under statutory authority granted by the 2000 Session of the Virginia General Assembly and have been in effect since March 27, 2002 without amendment. The passing of more than five years since the initial promulgation and the Board’s and the Virginia Transplant Council’s experience with the current regulations lead the Board to conclude that it is an appropriate time to consider amendments that will bring clarity and improve the efficiency and effectiveness of the Virginia Donor Registry.

### Substance

*Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.*

Amend 12VAC5-475-10 thru 12VAC5-475-90 to change references to the Virginia Organ and Tissue Donor Registry to the “Virginia Donor Registry” as determined by 2006 General Assembly amendments to §§ 32.1-292.2 and 32.1-297.1 of the Code of Virginia and to replace references to § 32.1-290, which was repealed by the 2007 General Assembly, with references to the *Revised Uniform Anatomical Gift Act* (§ 32.1-291 et seq.)

12VAC5-475-10 Definitions. Amend definitions of “Document of gift” to reference the donor registration form available on the save7lives.org website.

12VAC5-475-10 Definitions. Amend definitions to clarify that the Virginia Transplant Council has responsibility for creating, compiling, maintaining, and modifying the Virginia Donor Registry.

12VAC5-475-10 Definitions. Amend definitions to include “save7lives.org” as the official website that provides information on organ and tissue donation and provides a registration form to indicate a willingness to donate.

VAC5-475-40 Access. Clarify data requirements to require that the Virginia Transplant Council shall maintain and annually report the following information to the Board: (1) the number of unique individuals registered in the Donor Registry; (2) the number of recovered organ donors; (3) the number of recovered who were identified through the Registry; (4) the number of recovered tissue donors; (5) the number of recovered tissue donors who were identified through the Registry; (6) the number of recovered eye/cornea donors; (7) the number of recovered eye/cornea donors identified through the Registry; (8) the number of recovered organ, tissue, eye/cornea donors that were family initiated.

12VAC5-475-50 Registry membership. Amend to include that designees may assist individuals who complete a signed application and that persons may indicate their willingness to donate by completing the Donor Registration form available on the save7lives.org website.

12VAC5-475-60. Data to be recorded. Eliminate the recording of the telephone number in the Registry. Also eliminates the reference to the Registry Form (VTC 1) which has been replaced by registration via the web site [save7lives.org](http://save7lives.org) (see proposed amendments to 12VAC5-475-50).

## Alternatives

*Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.*

---

As a part of a periodic review, the department worked closely with the Virginia Transplant Council to determine if any amendments were needed to make the regulation consistent with current practices of administering and accessing the Virginia Donor Registry. The Board of Health, in conjunction with the Virginia Transplant Council, will consider alternative requirements and confirm that the proposed amendments to the existing regulations will simplify current regulations to be less burdensome, while also continuing to fulfill the Board's statutory mandate to protect the citizens of the Commonwealth.

## Public participation

*Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.*

---

The Board of Health is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the amendment of the proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the proposed amended regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the proposed amended regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the proposed amended regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Janice M. Hicks, Virginia Department of Health, 109 Governor Street, 7<sup>th</sup> Floor, Richmond, VA 23219, TEL: (804) 864-7662, EMAIL: [Janice.hicks@vdh.virginia.gov](mailto:Janice.hicks@vdh.virginia.gov), FAX: (804) 864-7670. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

In addition, the agency is seeking information on (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

A public hearing will not be held.

**Participatory approach**

*Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.*

The Board of Health, in conjunction with the Virginia Transplant Council, will use the participatory approach to develop and/or refine the proposed amendments to the regulations and may appoint committees composed of Board members, Virginia Transplant Council members, and non-members.

**Family impact**

*Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

Based upon its review and input received from users of the Virginia Donor Registry and the public, the Board of Health in conjunction with the Virginia Transplant Council will assess the impact any proposed amendments will have on the institution of the family and family stability. The goals of the Board include developing amendments that will not negatively impact (1) the authority and rights of parents in the education, nurturing, and supervision of their children, (2) the economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents, (3) the marital commitment, and (4) disposal family income.

**Periodic review - Public comment**

***If this NOIRA is not the result of a periodic review of the regulation, please delete this entire section.***

*If this NOIRA is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 36, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.*

No comments were received from the public during the recent periodic review. However during the review, the Virginia Transplant Council worked closely with the Virginia Department of Health to review the regulations and develop amendments that enhance the clarity of the regulations and achieve improvements that will be reasonable, prudent and will not impose an unnecessary burden on users of the Virginia Donor Registry or the public.

This regulation is necessary to administer the Virginia Donor Registry which will protect the public health, safety and welfare. The proposed regulation amendments to the existing regulations will simplify current regulations to be less burdensome, while also continuing to fulfill the Board's statutory mandate to protect the citizens of the Commonwealth by regulating the implementation of the Virginia Donor Registry.

### Periodic review - Discussion

***If this NOIRA is not the result of a periodic review of the regulation, please delete this entire section.***

*If this NOIRA is the result of a periodic review or if the periodic review is to be performed in combination with the NOIRA, please include a discussion of the agency's consideration of: (1) the continued need for the rule; (2) the complexity of the regulation; (3) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, include a discussion of the agency's determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.*

---

As a result of this periodic review, it has been determined that (1) this regulation is necessary to administer the Virginia Donor Registry which will protect the public health, safety, and welfare of the residents of the Commonwealth. (2) The proposed amendments to the regulations will reduce complexity by clarifying current practices of the Virginia Donor Registry. (3) This regulation does not appear to overlap, duplicate, or conflict with federal or state law or regulations. (4) This regulation has been in effect since March 27, 2002. Since the regulation was first enacted, the use of web technology has increased significantly. As a result a new web site, save7lives.org, has been developed and is now a mechanism for donor registration. The last Periodic Review public comment period closed on November 11, 2007.